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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,636	01/21/2004	Bernard Frank Bishop	PC22004B	3343

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EXAMINER	
MCINTOSH III, TRAVISS C	
ART UNIT	**PAPER NUMBER**
1623	
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06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,636	BISHOP, BERNARD FRANK	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-8 and 10-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-8 and 10-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed 3/28/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 13 and 19 have been amended.

Claims 2, 5, and 9 have been canceled.

Remarks drawn to rejections of Office Action mailed 12/28/2006 include:

112 1st paragraph rejection: which has been overcome by applicant's amendments and has been withdrawn.

103(a) rejection: which has been maintained for reasons of record.

An action on the merits of claims 1, 3-4, 6-8, and 10-19 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 as amended is drawn to a method "of treatment or prophylaxis of parasitic infestation of flea, heartworm or treatment of tapeworm in a mammal...", which is confusing. The claim would be more favorably read as "a method of treatment or prophylaxis of a parasitic flea or heartworm infestation or treatment of a parasitic tapeworm infestation in a mammal...", or language of the like.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 3-4, 6-8, and 10-19 under 35 U.S.C. 103(a) as being unpatentable over Harvey (WO 98/06407) and Lukas et al. (US 2002/0028780), in view of Andrews et al. (US 4,988,696) is maintained for reasons of record.

Claim 1 is drawn to a formulation comprising selamectin at about 1-16% w/v and praziquantel at about 0.5-10% w/v, together with a carrier, diluent, or adjuvant. Claim 8 provides praziquantel is present at about 3-9% w/v, and claim 3 provides praziquantel is present at about 6%. Claim 4 provides there is also an ether and optionally a solvent. Claim 6 provides selamectin is provided at around 6-12 mg/kg and praziquantel at up to 18 mg/kg. Claim 7 provides the selamectin is present at about 6-12% w/v. Claim 10 provides that DEGMME or DPGMME is present. Claim 11 provides that a solvent of either ethanol or isopropanol is present. Claim 12 provides for a specific formulation. Claims 13-18 are drawn to methods of treating or preventing flea or heartworm infections, or treating tapeworm infections by administering the formulation of claim 1. Claims 14-17 state the drugs are delivered via the same route, or a different route, and delivered in the same formulation, or in different formulations. Claim 18 provides the method is practiced on a cat. And claim 19 is drawn to a kit comprising selamectin and praziquantel and a

carrier. It is noted that the written instructions of claim 19 are of no patentable import to the claim.

Harvey teaches of a veterinary composition containing an effective amount of praziquantel, an effective amount of at least one macrolide anthelmintic selected from avermectins and milbemycins, a suitable organic solvent and a carrier. The praziquantel is taught to be present in an amount ranging from 1-10% w/v (see page 2, lines 20-21). Harvey also teaches praziquantel can be combined with any compound of the avermectin group to achieve the purpose of their invention (page 19, lines 19-20). What is not taught is to specifically combine it with selamectin.

Lukas et al. teach an antiparasitic formulation comprising 0.1-50% w/v of an avermectin or milbemycin having endo- or ectoparasitic activity, 1-50% w/v of an ether, optionally an antioxidant, and a solvent (see page 1, column 1). Lukas et al. disclose that the preferred avermectin in their formulation is selamectin and the preferred ether is DEGMME or DPGMME (see page 1, column 2). Additionally, Lukas et al. teach that the preferred solvent is ethanol or isopropanol (page 2, column 1). Lukas et al. also teach that the antioxidant present can be BHT at a level of less than 0.2% w/v. Lukas et al. teach that their formulations can be prepared for topical or spot-on use, and administered to a dog or cat (page 1, column 2- page 2, column 1). What is not taught is to add praziquantel.

Andrews et al. teach of topical formulations and methods of treating worm diseases by topically applying praziquantel in amounts of from 0.1-5mg/kg body weight (see column 2, lines 25-30).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the active agents, selamectin and praziquantel, to form a single composition with these references before them, and use them in the manner in which they are known to be used in the art, as an anti-helminth. One would have been motivated to combine praziquantel and selamectin in a formulation in the claimed amounts because the agents individually are know to be effective in those amounts. Moreover, one would have been motivated to combine the active agents because it is obvious to combine two compositions each of which is used for the same purpose, to form a new composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. ***In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*** (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also ***In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960)*** (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and ***Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992)*** (mixture of two known herbicides held prima facie obvious). In the instant case, Harvey teaches it is advantageous to combine two or more anthelmintics with different activity in one composition to obtain a composition having a broad spectrum of activity, and thus reduce the time spent treating the animal and thus reducing the stress on the animal. Andrews et al. and Lukas et al. teach that praziquantel and selamectin can each be delivered topically to animals. Moreover, Andrews et al. states that dermal administration is advantagous, as the animal does

not have to be held during treatment, as with injections, nor is there a risk of refusal of medication if administered in a food/orally (see column 2, lines 9-17).One would have been motivated to combine these agents to form a new composition which would be used for the very same purpose. The art teaches both drugs can be administered topically to the dermis, that combination therapy is encouraged to deliver more than one drug at a time, and that dermal application is advantageous due to ease of delivery. The art also teaches the drugs are effective in the concentrations claimed. As such, claims 1, 3-4, 6-8, and 10-19 are seen to be obvious in light of the above references.

Applicant's arguments filed 3/28/2007 have been fully considered but they are not persuasive. Argued is that Harvey relates to oral drenches containing praziquantel, which is not the same as a topical formulation, and thus one would not combine with Lukas et al (which teaches selamectin in topical formulations). However, Harvey et al. must be taken for what it teaches as a whole, and that is that praziquantel can be combined with avermectins (selamectin) (see claims). Additionally argued is that it would not be obvious to combine the agents because praziquantel is not known to be used for fleas; praziquantel is not known to be used for heartworms; and selamectin is not known to be used for tapeworms. That is, there is no reason to combine for the same purpose as they are allegedly not known to be used for the same purpose. However, Harvey bridges the gap by teaching that it is advantageous to have an agent for tapeworm when administering a macrolide endecticide (selamectin) (see page 1, lines 14-16). It is common practice to formulate veterinary preparations for both endo-and ectoparasites (see claim 21 of Lukas for example). Additionally argued is unexpected results of synergism.

However, this is not seen to be convincing. Trial A shows that both selamectin and praziquantel have efficacy against Dipylidium when used individually, the results of the combination would be expected to be additive, or slightly synergistic, as shown in the table. Likewise, Trial B shows a much higher percent efficacy for the same dose of praziquantel (1mg/kg) against the same tapeworms (89% efficacy in trial B vs. 74% efficacy in trial A), which is almost as high as the combination of selamectin and praziquantel in trial A, thus showing applicants results are not necessarily as synergistic as set forth, but rather obtaining various results based upon the experimentation. The art teaches the combination of praziquantel & selamectin. The art teaches that each can be used topically to treat parasites. It would be obvious to formulate the combination into a topical formulation to treat the parasites with these references before them.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
June 10, 2007

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623